FEB 25 2014

2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: November 13, 2013

510(k) Number: K133501

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Mia Hunt
Regulatory Product Specialist
Tel: 763-656-4300
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General Information

Trade Name	LeadLiner CS lead delivery system
Common / Usual Name	Catheter, Percutaneous
Classification Name	Class II – 870.1250
Predicate Device	K120158 - Lateral Vein Introducer Kit (Pressure Products)

Device Description

The LeadLiner CS lead delivery system (LeadLiner) is used to deliver pacing or defibrillator leads and consists of the LeadLiner delivery catheter and the LeadLiner inner catheter. It is packaged with a loading tool to assist in delivery of the two-catheter system and the lead through the hemostatic valve of the introducer sheath. It also includes a retention clip to hold the delivery and inner catheters together and allow the operator to manipulate the two catheters as a single system.

Intended Use / Indications

The LeadLiner CS lead delivery system is intended for the introduction and delivery of pacing or defibrillator leads.

Technological Characteristics

LeadLiner has similar physical and technical characteristics to the predicate device. Both devices are sterile, two-catheter systems designed to facilitate lead placement. The delivery or outer catheter components of both devices have a 9 French O.D, braid reinforcement, and are used with smaller inner catheters. The primary technological difference between LeadLiner and the predicate device is the removal mechanism. LeadLiner delivery catheter has a rapid-exchange,

pre-perforated design which allows it to be easily split from a delivered lead; the predicate device is removed by cracking the outer catheter hub and using a cutting tool to slice the catheter from the lead.

Substantial Equivalence and Summary of Studies

Technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence of safe and effective use of LeadLiner. LeadLiner is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Simulated use
- Bend radius
- Torque
- Tensile-Delivery catheter perforations

Results of the verification tests met the specified acceptance criteria and did not raise new safety or performance questions. Therefore, LeadLiner is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Vascular Solutions, Inc.
Mia Hunt
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K133501
Trade/Device Name: Leadliner CS Lead Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: January 6, 2014
Received: January 7, 2014

Dear Ms. Hunt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Linda J. Ricci -S for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133501

Device Name: LeadLiner CS lead delivery system

Indications for Use:

The LeadLiner CS lead delivery system is intended for the introduction of pacing or defibrillator leads.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda J. Ricci -S